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TECHNOLOGY CENTER R3700

REMARKS

The above amendment is submitted in response to the Examiner's Action in the parent case of 29 March 2002.

Applicant has submitted a new set of claims 27-37 which is believed to distinguish the invention sought for patenting from the prior art references, in particular the Pratt, Lau, Chin, and Dardik references.

The Examiner rejected the prior claims 14-20, 22 and 26 as being unpatentable over Pratt in view of Dardik under 35 U.S.C. §103 (a). Claims 21, 23-25 were rejected as being obvious over Pratt and Dardik and further in view of Lau and Chin.

Applicant is presenting newly submitted independent claim 27 which includes language of prior claim 14 with the addition of a removable stent located in the lumen of the preserved vessel. It is believed that this combination is not shown by any of the references taken alone or in combination.

Pratt discloses the use of freeze-dried microarterial allografts from rats and rabbits. Studies by Pratt and Chow indicate that freeze-dried tissues tend to prevent immune response when later used as implants as allografts and autografts in rats. Pratt states that freeze drying only retarded the process of post immune reaction, but seemed to prevent an immune response to the

allografts studied. The Chow reference, page 704 stated that the patency rate of freeze-dried rats was as high as 85 percent at two weeks but dropped 55 percent in three months. Chow goes on to say that more than 60 percent of the graphs showed dilation with occasional aneurysm formation. Also, most of the blocked graphs became disintegrated at three months due to fibrosis. Thus, although the initial assessment of the Chow graphs was favorable, over longer period of time it appears that the vessels deteriorated to the point where usefulness is questionable. Neither Pratt nor Chow describes the use of a stent in the preserved vessel.

Dardik teaches that placental and umbilical tissues can be used as a source for microarterial vessels for reconstructive surgery. However, Dardik used tanning procedures to remove surface antigens. Dardik also shaped the vessels with a mandrel and used tanning chemicals in combination with a polyester mesh to support the graft. Thus, the end result of the Dardik procedure is a hard and rigid vessel which does not possess high patency and represents a chemically denaturing. This vessel is unlike that claimed by Applicant in the present application.

The Chin reference teaches the use of a bifurcated stent graft which is used in endoscope grafting. The stent used by Chin is a permanent element. In contrast, the stent employed by Applicant is removable from the lumen of the isolated vessel. This feature is not shown by Chin.

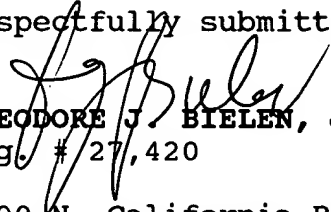
The combination of Pratt and Dardik would only point Pratt in the direction of using placental and umbilical tissue as a source for microarterial grafts there is no teaching in either Pratt or Dardik to directly lyophilize a human umbilical cord and/or achieve combined and preserved vessel of this sort with a removable stent.

The addition of Chin would produce a preserved vessel which has a permanent stent that would certainly interfere with patency and greatly reduce the flexibility of such vessel. Such vessel would be more in the line of a Dardik denatured vessel which is not one that is claimed by Applicant.

It should be noted that the use of a removable stent allows the preserved vessel to be easily handled in the freeze-drying process and stored thereafter. Also, the stent maintains the lumen through the vessel and prevents collapse or pinching of the vessel in the lyophilization process and thereafter. Moreover, the use of Applicant's stent prevents the employment of a catheter later to open a lumen of a lyophilized human umbilical or placental vessel prior to use. The use of a catheter is more likely to damage the endothelial wall within the vessel causing roughness or breakage and ultimately resulting in failure of the graft when transplanted to a human.

It is believed that the application as amended is now in condition for allowance and the passing to issue of the application at an early date is earnestly solicited.

Respectfully submitted,


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